

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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[Docket No. 00N-1511]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Petition for Administrative Reconsideration of Action

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Petition for Administrative Reconsideration of Action—21 CFR 10.33 (OMB Control Number 0910–0192)—Extension

The regulations in 21 CFR 10.33, issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)), set forth the format and procedures by which an interested person may petition the Commissioner of Food and Drugs (the Commissioner) for reconsideration of an agency action. A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or adequately considered by the Commissioner. Each petition must be submitted no later than 30 days after the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions.

In the **Federal Register** of September 25, 2000 (65 FR 57615), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

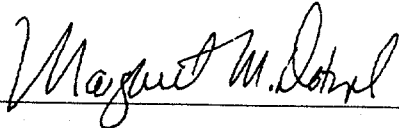
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.33(b)	12	1	12	10	120

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this collection of information is based on agency records and experience over the past 3 years. Agency personnel handling the petitions for administrative

reconsideration of an action estimate approximately 12 requests being received by the agency annually, each requiring an average of 10 hours preparation time.

Dated: December 27, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy.

**CERTIFIED TO BE A TRUE
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[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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